

**Product PN** 1214604, 1214568, 1214669, 1225884, 3037376

**Mod. 984**

**Description** 0.8 µm Polyethersulfone Filtration Membrane Discs and Sheets

**Rev. 01**

## 0.8 µm Polyethersulfone (PES) Filtration Membrane Discs and Sheets









<b>PRODUCT DESCRIPTION</b>	0.8 µm PES roll stock			
	<b>Part Number</b>	<b>Geometry</b>	<b>Dimensions</b>	<b>Packaging</b>
	1214604	Disc	25 mm	100/Pk
	1214568	Disc	47mm	100/Pk
	1214669	Disc	90 mm	25/pk
	1225884	Sheet	200 x 200 mm	5/pk
	3037376	Sheet	30 cm x3 m	1/pk
<b>MANUFACTURE NAME</b>	GVS North America, Inc. 63 Community Drive Sanford, ME 04073 Phone: +1.866.736.1250 Email: <a href="mailto:CustomerCareGVSLs@gvs.com">CustomerCareGVSLs@gvs.com</a> Website: <a href="http://www.gvs.com">www.gvs.com</a>			
<b>INTENDED USE/ APPLICATION</b>	Typical Applications: <ul style="list-style-type: none"> <li>• Environmental water studies</li> <li>• Industrial water filtration</li> <li>• IV filters</li> <li>• IV drug delivery</li> <li>• TPN delivery</li> </ul>			
<b>MATERIALS</b>	Film: Polyethersulfone (PES)  Regulatory Documentation Required: <ul style="list-style-type: none"> <li><input type="checkbox"/> Biocompatibility according ISO 10993-1</li> <li><input type="checkbox"/> IMDS</li> <li><input checked="" type="checkbox"/> Rohs, directive 2002/95/CE</li> <li><input checked="" type="checkbox"/> BSE/TSE, directive 2003/32/CE</li> <li><input type="checkbox"/> DEHP plasticizer and latex free</li> <li><input type="checkbox"/> Aging</li> <li><input checked="" type="checkbox"/> Reach 1907/2006/CE (hazardous substances regulation)</li> <li><input type="checkbox"/> Dir. 67/548/CE and Reg. 1272/2008/CE (medical sector dangerous substances)</li> <li><input checked="" type="checkbox"/> Conflict minerals</li> <li><input checked="" type="checkbox"/> USP Class VI</li> </ul>			
<b>PRODUCT CHARACTERISTICS</b>	<ul style="list-style-type: none"> <li>• USP Class VI compliant</li> <li>• Hydrophilic</li> <li>• Maximum operating temperature: 266°F (130°C)</li> <li>• Autoclavable</li> <li>• Broad sealing compatibility, including, ultrasonic, heat, radio frequency and insert molding</li> <li>• Metal Ions, Chloride and Sulfates: Not detectable (Analytical screen by ICP)</li> </ul>			
<b>PRODUCT</b>	5 years in normal storage conditions:			

# PRODUCT SPECIFICATION

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<b>SHELF LIFE</b>	Store the product at room temperate, in a dry place, free of dust and not exposed to direct sunlight.
<b>STERILIZATION</b>	<p>This is a non-sterile product, compatible with these sterilization techniques*:</p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> EtO</li> <li><input checked="" type="checkbox"/> Gamma (25 kGy)</li> <li><input checked="" type="checkbox"/> Autoclave (121°C)</li> <li><input checked="" type="checkbox"/> eBeam</li> </ul> <p><i>*user has the responsibility to validate their process</i></p>

<b>PACKAGING AND LABELING</b>	<table border="1"> <thead> <tr> <th>Product</th> <th>Interior package</th> <th>Exterior package</th> </tr> </thead> <tbody> <tr> <td>13, 25, 47 mm Discs</td> <td>Discs separated by blue paper in a thermoformed tray</td> <td>Clear/white plastic box</td> </tr> <tr> <td>90, 142, 293 mm Disc</td> <td>Discs separated by blue paper</td> <td>Round container</td> </tr> <tr> <td>150 x 50 mm, 200 x 200 mm sheet</td> <td>Sheets separated by blue paper</td> <td>White mailer</td> </tr> <tr> <td>30 cm x 3 m</td> <td>Single sheet wrapped on a plastic core</td> <td>Cardboard box</td> </tr> </tbody> </table>	Product	Interior package	Exterior package	13, 25, 47 mm Discs	Discs separated by blue paper in a thermoformed tray	Clear/white plastic box	90, 142, 293 mm Disc	Discs separated by blue paper	Round container	150 x 50 mm, 200 x 200 mm sheet	Sheets separated by blue paper	White mailer	30 cm x 3 m	Single sheet wrapped on a plastic core	Cardboard box
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<ul style="list-style-type: none"> <li>• Each configuration will be labeled with: <ul style="list-style-type: none"> <li>○ Quantity</li> <li>○ Product item code and description</li> <li>○ Manufacturing date</li> <li>○ Lot number</li> <li>○ Storage conditions</li> </ul> </li> </ul> <p>Example label below:</p> <div style="border: 1px solid black; padding: 10px; text-align: center;">  <p>GVS North America Sanford, ME 04073 - USA www.gvs.com +1 866-736-1250</p>  <p><b>Polyethersulfone (PES) Membrane</b> Disk diam. 25 mm, PES 0.8 µm</p> <table border="0"> <tr> <td><b>REF</b></td> <td>1214604</td> </tr> <tr> <td><b>LOT</b></td> <td>SAMPLE</td> </tr> <tr> <td><b>QTY</b></td> <td>100 EA</td> </tr> <tr> <td></td> <td>Jan/2018</td> </tr> </table> <p>130 °C </p> <p>MADE IN USA Rev. 0</p> </div>	<b>REF</b>	1214604	<b>LOT</b>	SAMPLE	<b>QTY</b>	100 EA		Jan/2018								
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<b>CERTIFICATE OF COMPLIANCE</b>	A conformity declaration will be sent to the customer for each shipment with lot number and date of manufacture. The Quality management system is in compliance with ISO 9001.
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<b>PERFORMANCE REQUIREMENTS</b>	<b>Acceptance Requirement</b>		<b>Standard Test Method</b>
	1	Thickness	110-150 µm


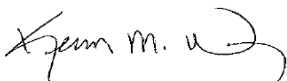
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	2	Water Flow Rate	Min 80 mL/min/cm <sup>2</sup> @ 10 psi	ASTM F 316-03 (2011)
	3	Bubble Point	13-28 psi (0.8-1.9 bar)	ASTM F 316-03 (2011)

This material specification describes the properties of product above indicated.  
 This document contains general requirements, material description, drawing references, defect specification, and biological material requirements.

## REVISIONS AND APPROVALS:

DATE	REV	REASON FOR CHANGE	ISSUED AND CONTROLLED BY: (name /function and signature)	APPROVED BY: (name /function and signature)
6/8/18	0	Initial Release	Gil Tavares/Process Development Engineer 	Kevin Wrigley/Director of Quality 

## CUSTOMER APPROVAL:

We accept this material specification as a part of the agreed terms of delivery.

Company name \_\_\_\_\_

Approved by: \_\_\_\_\_  
 (Name, Function) (Signature)

Date \_\_\_\_\_  
 (Company stamp)

Please send back this document signed for approval. If we will not receive this specification signed, we consider the first order placed as implicit approval.